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| APPLICATION NO. | FILING DATE     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |  |
|-----------------|-----------------|----------------------|---------------------|-----------------|--|
| 10/646,802      | 08/25/2003      | Bijan S. Khirabadi   | 102691.02           | 1323            |  |
| 25944 7         | 7590 01/11/2006 | EXAMINER             |                     |                 |  |
| OLIFF & BE      | RRIDGE, PLC     | SAUCIER, SANDRA E    |                     |                 |  |
| P.O. BOX 199    |                 |                      | ART UNIT            | PAPER NUMBER    |  |
| ALEXANDKI.      | A, VA 22320     | 1651                 |                     |                 |  |

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |  |   | Application N  | 0.  | Applicant(s)   |              |  |  |  |
|---|--|---|--|---|--|--------------|--|--|--|
| Office Action Summary   |  | 10/646,802  |  | KHIRABADI ET AL.  |  |              |  |  |  |
|   |  | Examiner  |  | Art Unit  |  |              |  |  |  |
|   |  |   | Sandra Saucie  |   | 1651   |              |  |  |  |
| Period fo   | The MAILING DATE of this commu<br>or Reply   | nication app  | ears on the cov  | er sheet with the c   | orrespondence ac   | dress        |  |  |  |
| WHIC<br>- Exte<br>after<br>- If NC<br>- Failu<br>Any  | ORTENED STATUTORY PERIOD F<br>CHEVER IS LONGER, FROM THE Management of time may be available under the provisions<br>SIX (6) MONTHS from the mailing date of this composition of the period for reply is specified above, the maximum is<br>reto reply within the set or extended period for reply received by the Office later than three months and patent term adjustment. See 37 CFR 1.704(b). | MAILING DA<br>s of 37 CFR 1.13<br>munication.<br>tatutory period w<br>y will, by statute, | ATE OF THIS (<br>36(a). In no event, ho<br>rill apply and will expi<br>cause the application | COMMUNICATION wever, may a reply be tim re SIX (6) MONTHS from to become ABANDONE | J.  lely filed  the mailing date of this c  (35 U.S.C. § 133). |              |  |  |  |
| Status  |  |   |  |   |  |              |  |  |  |
| 1)□   | Responsive to communication(s) file  | ed on   |  |   |  |              |  |  |  |
| ·   | ·  |   | -·<br>action is non-fi   | nal.  |  |              |  |  |  |
| 3)□   |  | •   |  |   | secution as to the   | e merits is  |  |  |  |
| ,—  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |   |  |   |  |              |  |  |  |
| Dispositi   | on of Claims   |   |  |   |  |              |  |  |  |
| 4)⊠   | 4)⊠ Claim(s) <u>1-25</u> is/are pending in the application.  |   |  |   |  |              |  |  |  |
| ·   | 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |  |   |  |              |  |  |  |
| 5)[   | 5) Claim(s) is/are allowed.  |   |  |   |  |              |  |  |  |
| 6)□   |  |   |  |   |  |              |  |  |  |
| 7)  | <u>_</u>   |   |  |   |  |              |  |  |  |
| 8)⊠   | Claim(s) <u>1-25</u> are subject to restrict   | ion and/or e  | election require   | ment.   |  |              |  |  |  |
| Applicati   | on Papers  |   |  |   |  |              |  |  |  |
| 9)□   | The specification is objected to by the  | ne Examinei   | r.   |   |  |              |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |  |   |  |   |  |              |  |  |  |
|   | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |  |   |  |              |  |  |  |
|   | Replacement drawing sheet(s) including   | g the correcti  | on is required if  | he drawing(s) is obj  | ected to. See 37 C   | FR 1.121(d). |  |  |  |
| 11)   | The oath or declaration is objected t  | o by the Ex   | aminer. Note tl  | ne attached Office  | Action or form P   | ΓΟ-152.      |  |  |  |
| Priority ι  | ınder 35 U.S.C. § 119  |   |  |   |  |              |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of: |  |   |  |   |  |              |  |  |  |
|   | <ul> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> </ul>  |   |  |   |  |              |  |  |  |
|   | 3. Copies of the certified copies of the priority documents have been received in this National Stage  |   |  |   |  |              |  |  |  |
|   | application from the Internation   |   |  |   |  |              |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.                                    |  |   |  |   |  |              |  |  |  |
|   |  |   |  |   |  |              |  |  |  |
| Attachmen   | t(s)   |   |  | _   |  |              |  |  |  |
|   | e of References Cited (PTO-892)  |   | 4) [   | 4) Interview Summary (PTO-413) Paper No(s)/Mail Date                              |  |              |  |  |  |
|   | e of Draftsperson's Patent Drawing Review (F<br>nation Disclosure Statement(s) (PTO-1449 or  |   | 5) [   | Notice of Informal P  |  | O-152)       |  |  |  |
| ,   | r No(s)/Mail Date  |   | · –  | 6) Other:   |  |              |  |  |  |

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## **DETAILED ACTION**

Claims 1-25 are pending and subject to restriction.

## Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-22, drawn to a method of devitrifaction of tissues or organs, classified in class 435, subclass 1.3, for example and others.
- II. Claims 23-25, drawn to a method of vitrification and devitrification of tissues or organs, classified in class 435, subclass 1.3, for example and others.

The inventions are distinct, each from the other because of the following reasons:

The processes are distinct from one another because they recite different and distinct steps which have different and distinct starting materials. For example, the method of Group I requires a vitrified tissue or organ, while the method of Group II requires a non-vitrified organ or tissue as starting material.

The several inventions listed above are independent and distinct from one another as they have acquired a separate status in the art and require independent searches, particularly with regard to the literature searches. Clearly, a reference which would anticipate one of the above groups would not necessarily anticipate or even make obvious any of the others.

An undue burden would ensue from the examination of multiple methods which have distinct steps and end points. Burden lies not only in the search of US Patents, but in the search for literature and foreign Application/Control Number: 10/646,802

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patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.

Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

## **Election of Species**

Further, once applicant has elected Group I or II for examination, applicant must further elect from the following species as this application contains claims directed to the following patentably distinct species of the claimed invention: organs or tissues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such

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evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866–217–9197 (toll–free).

Sandra Saucier Primary Examiner

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